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Registration Decision RD2014-15

Metallic Copper

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Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6604-E2
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

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Registration Decision for Metallic Copper

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Copper TGAI and Antimicrobial Copper Alloys Group I, II, III, IV, V and VI, containing the technical grade active ingredient metallic copper, to be used to manufacture products with inherent antimicrobial properties.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2013-23, *Metallic Copper*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for metallic copper and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2013-23. This decision is consistent with the proposed registration decision stated in PRD2013-23.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2013-23, *Metallic Copper* that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is Metallic Copper?

Metallic Copper, in the form of six different alloys, may be used to manufacture products with inherent antimicrobial properties. Although the mode of action has not been confirmed, scientific literature suggests that the toxicity of surfaces made of solid copper involves the release of copper ionic species toxic to the cell membrane, and the generation of superoxide resulting in arrested respiration and DNA breakdown as the first stages of cell death.

Health Considerations

Can Approved Uses of Metallic Copper Affect Human Health?

Metallic copper is unlikely to affect human health when it is used according to label directions.

Potential exposure to metallic copper may occur when handling, installing, and touching products fabricated with the end-use products, Antimicrobial Copper Alloys Group I, Antimicrobial Copper Alloys Group II, Antimicrobial Copper Alloys Group III, Antimicrobial Copper Alloys Group IV, Antimicrobial Copper Alloys Group V, and Antimicrobial Copper Alloys Group VI (hereafter referred to as Antimicrobial Copper Alloys Group I to VI). When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

The technical grade active ingredient, metallic copper, was of low acute toxicity via the dermal route of exposure. Metallic copper was non-irritating to the skin and eyes, but instances of acute contact dermatitis (ACD)[5] in sensitive individuals have been reported in the open literature.

[5] According to the Canadian Centre for Occupational Health and Safety (CCOHS), the current number of ACD cases in Canada is unknown but contact dermatitis, marked by red, itchy inflammation of the skin, is reversible and is not life-threatening

The acute toxicity of the end-use products, Antimicrobial Copper Alloys Group I to VI, were low via the dermal route of exposure. They were non-irritating to the skin and eyes, but cause allergic skin reaction; consequently, the hazard signal words "Potential skin sensitizer" are required on the label.

Metallic copper did not cause effects in developing young and did not damage genetic material.

The risk assessment protects against the effects of metallic copper by ensuring that the level of human exposure is well below the lowest dose at which effects occurred in animal tests.

Residues in Water and Food

Dietary risks from food and drinking water are not of health concern.

The proposed uses of Antimicrobial Copper Alloys Group I to VI are not food or feed related. Dietary risks from food and drinking water are negligible.

Occupational Exposure

Occupational risks are not of concern when Antimicrobial Copper Alloys Group I to VI are used according to the proposed label directions, which include protective measures.

A risk assessment conducted for individuals handling and installing products fabricated with Antimicrobial Copper Alloys Group I to VI indicated that risk for adults is not of concern when the products are used according to label directions.

Environmental Considerations

An environmental assessment was not required for this application based on the proposed use pattern.

Value Considerations

What Is the Value of Antimicrobial Copper Alloys Group I to VI?

The articles manufactured with the Antimicrobial Copper Alloys Group I to VI will have a surface providing continuous sanitizing action.

Because the antimicrobial activity comes from the metal itself, the action is continuous and cannot be removed or wiped off from the surface, while spray sanitizers have to be re-applied often, especially if the treated surfaces are touched or contaminated frequently during a day. These alloys will also provide a supplemental antimicrobial action between routine cleanings. Since the copper alloys are solids, no chemicals will leach from their surface upon contact.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

No further risk-reduction measures are required.

Other Information

The relevant test data on which the decision is based (as referenced in the Proposed Registration Decision PRD2013-23, *Metallic Copper*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[6] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[6] As per subsection 35(1) of the *Pest Control Products Act*.